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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,324	01/04/2002	H. William Bosch	029318-0107	2223

31049 7590 06/07/2007

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	**PAPER NUMBER**
1616	

MAIL DATE	DELIVERY MODE
06/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/035,324	BOSCH ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *15-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/06/07 has been entered.

Receipt is acknowledged of the Amendments and remarks filed on 03/06/07 and the supplemental Amendments filed on 03/22/07. Claims 1-14 have been amended, no claims cancelled or added and claims 15-34 remain withdrawn. Accordingly claims **1-14** are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 4-7 are indefinite for reciting an absolute term next to an approximate term. In other words the terms "less than" and "about" can not, at the same time identify a range or amount.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiedmann et al (5,747,001) in view of Westesen et al (6,207,178 B1).

Wiedmann et al teach aerosols containing droplets of an aqueous **dispersion** of nanoparticles of insoluble **beclomethasone** particles having a surface modifier on the surface thereof. Representative examples of surface modifiers include gelatin, bezalkonium chloride, PVA, sorbitans, etc (see col. 3, line 30 to col. 4, line 45). A suitable surfactant is **tyloxapol** (see col. 4, lines 49-60), the particles are preferably less than 400 nm in size, or more preferably less than 250 and most preferably **less than 100 nm** in size (see col. 6, lines 8-15 and col. 10, lines 25-35). The process of making such nanoparticles includes attrition and filteration (see col. 7, lines 18-21). It is disclosed that the concentration of the beclomethasone in the liquid medium can vary from about 0.1 to 60%, and preferably from 5-30% (w/w) (see col. 6, lines 19-22). Weidmann discloses that the surface modifies can be present in the formulation in an amount from 0.1-90% or preferably from 20-60% based on the total weight of the dry

particles (see col. 6, lines 23-28 and col. 10, lines 40-55). Wiedmann lacks teachings on sterile filteration.

Westesen et al teach solid particles of bioactive agents and methods for the manufacture and use thereof. The disclosure is in the area of administration forms and delivery systems for **drugs**, vaccines and other biologically active agents such as fungicides (see col. 1, lines 60-65). A small particle size is also required for the targeting of drugs (col. 3, lines 15-21). Since SLPs can be prepared down to a particle size of **about 50 nm**, they possess the opportunity of axtravasation through fenestrations of the endothelial wall. Thereby, drugs can be targeted to extravascular sites such as the bone marrow (col. 6, lines 57-65).

Westesen et al teaches suspensions of micron and submicron particles of biodegradable lipids solid at room temperature to suspensions of particles of meltable bioactive substances to lyophilizates thereof and to methods for the manufacturing thereof (col. 8, line 66 to col. 9, line 4). The suspensions are stabilized by amphiphatic compounds. Suitable stabilizers include **tyloxapol** (see paragraph bridging cols. 9 and 10). The aqueous phase in which the SLPs are dispersed can contain water-soluble or dispersable stabilizers (see col. 10, lines 9-14). Substantces particularly suitable for the entrapment into SLPs are drugs such as cortisone, dexamethasone, etc (see col. 10, lines 20-56). The bioactive substances can be dissolved, solubilized or dispersed in the matrix and/or in the stabilizer layers surrounding the particle matrix, and/or can be adsorbed to the surface of SLPs (see col. 10, lines 61-66).

Westesen et al disclose the steps in the manufacture of the solid particles which includes sterile filteration of the dispersion. It is disclosed that after homogenization the **dispersion** can be sterilized by standard techniques such as autoclaving or **filteration through a 0.2 micron sterile filter** provided that the particles are small enough not to be retained by the filter (see col. 11, lines 34-40).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have implemented the sterile filteration method as taught by Westesen et al in the formulations and process of Wiedmann, since Wiedmann teaches filteration of nanoparticles of beclomethasone and tyloxapol. In other words, one of ordinary skill in the art would have been motivated to implement sterile filteration of Westesen et al instead of simple filteration of Wiedmann because sterilization of formulations is beneficial to recipients. It has been clearly shown that a combination of Weidmann and Westesen et al meets each and every limitation of the instant claims.

Response to Arguments

Applicant's arguments with respect to claims 1-14 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian
Patent Examiner
June 04, 2007